DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) OMB No. 0990-0115
NATIONAL INSTITUTES OF HEALTH (NIH)
NATIONAL INSTITUTE OF ALLERGY AND INFECTIUS DISEASES (NIAID)

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 541710 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** [N/A]
NIH-NIAID-DMID-03-34	[ ] Yes [X] No		

TITLE:
Biodefense and Emerging Infections Research Resources Program

Issue Date:	***Due Date:***	***Technical Proposal Page Limits:***
December 9, 2002	***Time:*** **March 20, 2003 4:00 PM, EST**	[X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:	[X] ***We reserve the right to make awards without discussion.***	
Jacqueline C. Holden Senior Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	***NO. OF AWARDS:*** [X] Only 1 Award [ ] Multiple Awards	***PERIOD OF PERFORMANCE:*** 7 years beginning on or about 09/30/2003

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT -- Janet M. Mattson --COLLECT CALLS WILL NOT BE ACCEPTED--

Telephone: ***Direct*** **301-496-0993** ***Main*** **301-496-0612**	***Fax*** **301-480-5253**	***E-Mail*** **jm32u@nih.gov**

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Background
Biodefense and Emerging Infections Research Resources Program (BRP)
DMID-03-34

The purpose of this contract is to support the National Institutes of Health (NIH) Biodefense and Emerging Infectious Diseases Resource Program (Biodefense Resource Program, BRP), in achieving its goal of providing unique and quality assured Biodefense-related reagents and resources to the scientific community. This program will provide quality-assured reagents and resources to facilitate the understanding of the pathogenesis of NIAID Category A, B & C Priority Pathogens http://www.niaid.nih.gov/dmid/biodefense/bandc_priority.htm and emerging infectious disease organisms http://www.niaid.nih.gov/factsheets/eid.htm, and aid in the development and evaluation of vaccines, therapeutics and diagnostics for these organisms. The BRP will coordinate access to reagents not held in the Program. Long term, it is anticipated that that the BRP will become the Federal government's national resource and clearinghouse for specimens, reagents, and information on these organisms. By centralizing this function, access to and use of these materials can be governed and quality control of the reagents can be insured.

An important rate-limiting step in basic and translational research is the identification and distribution of state-of-the-art reagents and technology. To address this need, the National Institute of Allergy and Infectious Diseases (NIAID) is establishing the Biodefense and Emerging Infectious Diseases Resource Program (BRP). The BRP will acquire, authenticate, store, and distribute state-of-the-art research and reference reagents, standardized panels, and will provide current information through print and electronic media to facilitate research and product development for biodefense and emerging infectious diseases. These materials and information will be distributed to qualified investigators for the cost of shipping. Additionally, the BRP will collect information about Biodefense-related reagents and standards and will disseminate this information through print, electronic media, and workshops; enhance technology transfer through development and publication of methods; and facilitate commercial development of reagents through proactive communication with biotechnology and pharmaceutical companies. It is anticipated that many of these goals will be met by the use of sub-contractors, purchase orders and donations. Reagent contributors and users include scientists that meet the Federal registration criteria (Attachment A-1) and are employed by the academic and non-profit institutions, NIH, Centers for Disease Control and Prevention (CDC), Department of Defense, other Federal Agencies, and from industry.

Statement of Work
Biodefense and Emerging Infections Research Resources Program (BRP)
DMID 03-34

Independently and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below.

Specifically, the Contractor shall:

1. **IDENTIFY, ACQUIRE, AND PRODUCE/EXPAND AND CLONE (AS NECESSARY) ORGANISMS AND REAGENTS**

   a. The Contractor shall actively and independently identify strains and clones of NIAID Category A, B & C Priority Pathogens http://www.niaid.nih.gov/dmid/biodefense/bandc_priority.htm, emerging infectious disease agents http://www.niaid.nih.gov/factsheets/eid.htm, and reagents that are not readily available, and prioritize their acquisition based upon the needs of the biodefense and emerging infectious diseases research community, availability and cost. The Contractor will not be engaged in any activities involving Category A Pathogens that require handling under Biosafety Level (BSL-4) safety and containment conditions http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf

   b. The Contractor shall acquire reagents after receiving approval by the Project Officer. The acquisition of reagents, including radioactive reagents (either by purchase or donation) shall be an ongoing endeavor.

   c. Reagents purchased shall be acquired through a competitive process whenever practicable in accordance with FAR Part 13 Small Purchase Procedures and also in accordance with the prior consent requirements of FAR Part 44.

   d. The Contractor shall keep proper documentation on file supporting:

      (1) the price reasonableness for all acquisitions; and
      (2) the criteria for evaluation and selection of all sources for reagent acquisitions.

   e. The Contractor shall produce reagents as needed after receiving approval by the Project Officer. Production of reagents includes expansion of renewable reagents, e.g., including cell lines, viruses, microorganisms and recombinant DNA.

   f. For the purposes of this contract, reagents include, but are not limited to, the following biological materials:

      - NIAID Category A, B & C Priority Pathogens, excluding pathogens and agents that require use of BSL-4 laboratory facilities
      - NIAID designated emerging infectious disease agents or organisms, excluding pathogens and agents that require use of BSL-4 laboratory facilities
      - genetically manipulated prokaryotic/eukaryotic cell lines
      - DNA libraries
      - DNA clones
      - body fluids and cells
      - proteins and synthetic peptides
      - monoclonal and polyclonal antibodies

   g. Reagents also refer to, but are not limited to:

      - antiviral and anti-infective drugs and therapeutics
      - chemicals
      - agents that modulate the immune system, vaccines
      - vaccine constructs and vaccine adjuvants
      - diagnostic tools and kits for detection and measurement

h. Materials produced under Good Manufacturing Practice (GMP) conditions can be obtained and stored, under conditions in compliance with GMP, after receiving the approval of the Project Officer.

i. The Contractor may be requested to acquire/distribute specialized animal models (e.g. transgenic mice) to be used as a live source of reagents for investigators (no housing of animals required).

j. The list provided above is for illustrative purposes and is not comprehensive.

2. **PROVIDE FOR QUALITY CONTROL OF REAGENTS**

a. The Contractor shall provide for quality control of reagents. Quality control includes assay and evaluation of reagents.

b. Assays shall include, but are not limited to:

- clonality
- purity
- sterility
- stability
- chemical composition
- solubility
- neutralization and infectivity assays
- High pressure liquid chromatography (HPLC)
- restriction enzyme analysis
- polymerase chain reactions
- immunoblotting
- *In Situ* hybridizations
- tritiated thymidine incorporation
- biological activity

c. For microorganisms, this may require typing and strain validation. The number and types of assays to be performed will require the prior approval by the Project Officer. The Contractor shall anticipate assays for, but not limited to the following:

(1) Biological reagents, including but not limited to:

- bacteria
- viruses
- fungi
- body fluids
- cells
- tissues
- cell lines
- lysates
- nucleic acids
- protein and peptide preparations including antibodies

(2) Chemical reagents, including but not limited to:

- nucleoside analogs
- antimicrobials
- chemicals and other compounds or natural products which may be used for developing therapies against NIAID Category A, B & C Priority Pathogens and emerging infectious disease organisms

(3) GMP produced material to be used for vaccine or therapeutics evaluation.

3. **PROVIDE STORAGE, PROCESSING FACILITIES AND RESOURCES**

a. The Contractor shall provide facilities and equipment to receive, handle, propagate, vial, weigh and store potentially hazardous organisms and reagents, and maintain their activity or viability under Biosafety Level 2 and 3 (BSL2 and 3) containment. BSL-4 facilities are not required under this contract. http://bmbl.od.nih.gov/contents.htm; http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

b. The facilities shall provide aseptic and/or sterile conditions as appropriate.

c. Vaccines, drugs, therapeutics and other materials produced under GMP or that may be destined for pre-clinical use, as specified by the Project Officer, shall be stored in a room separate from infectious biologics.

d. The Contractor shall:

(1) Provide suitable air-conditioned floor space sufficient for the installation, storage and maintenance of equipment and all items necessary for the BRP and distribution operation.

(2) Provide, maintain and operate facilities for the storage of bulk and packaged reagents at 2 to 8 degrees C., at -10 to -20 degrees C., at -70 to -90 degrees C., liquid nitrogen conditions; and all other items necessary for the BRP.

(3) Supply uninterruptible power to accommodate the refrigerators/freezers and other equipment. In addition, the Contractor shall house the units in an air-conditioned facility with the capacity to maintain a room temperature of 66 degrees to 72 degrees F, when all equipment is operational.

(4) Freezers shall be connected to a central alarm system monitored 24 hours per day. Emergency stand-by refrigerators and freezers shall be available in case of mechanical failure of storage space. The facility must have an auxiliary electric generator capable of operating all storage equipment, security systems and necessary lighting for at least 48 hours for back-up in the event of utility company power failure. Back-up generator must be tested monthly under continuous full load for at least one hour.

(5) Provide, maintain and operate surveillance systems to assure that the stored materials remain accessible only to authorized personnel. The Contractor should utilize state-of-the-art electronic security system with fail secure locking hardware to insure controlled access to all of the designated repository areas of the Contractor's facility. A minimum of three separate levels or layers of physical and electronic security shall be employed. These levels of security may be increased at any time during the life of the contract if the federal government's security guidelines for facilities is modified.

(6) Provide systems to assure the safety and electronic controlled access to all the NIAID Category A, B & C Priority Pathogens and emerging infectious disease agent related materials.

(7) Provide, maintain and operate procedures to track and catalog, at both the prime and subcontractor locations, the handling and manipulation of the stores of the NIAID Category A, B & C Priority Pathogens and emerging infectious disease agents and materials related to these agents. All computer systems must utilize state-of-the-art software firewalls, computer security systems and other computer software to prevent unauthorized access to the computer system and to prevent 'hacking' by those outside the secure system.

(8) Provide protective garments, equipment and sufficient training and monitoring to assure safe handling of toxic, biohazard, and potentially hazardous materials, including radioactive materials. **Specifically, the Contractor shall comply with all applicable health and safety regulations http://www.cdc.gov/od/ohs/biosfty/biosfty.htm while conducting the work set forth herein and follow the standards listed under Attachment A-1 to the Work Statement.**

(9) Provide facilities to weigh or dispense solid and liquid reagents into aliquots and labeled vials. Because of the nature of some of the reagents, facilities should be available for the appropriate handling of infectious agents and for hazardous materials, including radioactive materials.

(10) Provide a separate, locked, electronic-controlled restricted-access storage space (i.e., safe, approximately 15 cubic foot) at the appropriate temperature for hallucinogens, narcotics and any other reagent designated by the Drug Enforcement Administration as a dangerous and/or controlled substance compound. These materials will be subject to cataloging and tracking as described for the Category A-C agents (see #5 immediately above).

(11) Maintain 24-hour security to provide a secure environment for employees and materials within the facility.

(12) Provide an automated temperature monitoring system composed of individual temperature probes monitored 24 hours a day and controlled by a master computer, and identify measures to ensure that necessary personnel are notified in the event of a refrigerator/freezer malfunction. The Contractor shall be responsible for the immediate repair of malfunctioning equipment or for arranging for immediate repair.

(13) Provide appropriate storage for radioactive material per local, state and federal regulations.

(14) The personnel assigned to this project must be bonded and meet all Federal Regulations and registrations for access and handling licensing requirements for CDC Category A Agents (**http://www.bt.cdc.gov/agent/agentlist.asp**), the requirement of the Patriot Act (USA Patriot Act: Sec. 817. – Expansion of Biological Weapons Statute (http://www.ins.usdoj.gov/graphics/lawsregs/patriot.pdf) and access to Select Agents (Appendix A to Part 72, CFR 42, (**http://www.cdc.gov/od/ohs/lrsat/p54605.pdf**) prior to beginning work on this contract.

4. **ESTABLISH AND IMPLEMENT A SYSTEM TO OVERSEE AND MANAGE THE DISTRIBUTION OF CDC CATEGORY A-C AGENTS. OBTAIN APPROVALS AND ASSURANCES NECESSARY TO DISTRIBUTE ALL STORED REAGENTS**

a. Establish a system that complies with Federal and State regulations governing access, distribution within a facility, transport, and use of CDC Category A-C Agents (http://www.bt.cdc.gov/Agent/Agentlist.asp)

b. Establish a system to verify that all Investigators and Institutions requesting agents or reagents are in compliance with the requirements of the Patriot Act (USA Patriot Act: Sec. 817. –Expansion of Biological Weapons Statute http://www.ins.usdoj.gov/graphics/lawsregs/patriot.pdf).

c. Distribute reagents to approved investigators and institutions in accordance with operating procedures in compliance with all Federal and State regulations and approved by the Project Officer. The Contractor shall consult with the Project Officer in questionable cases.

d. As requested by the Project Officer, develop form letters to be used for acceptance or refusal of reagent requests.

e. Distribute materials only to institutions that, in addition to other assurances, execute agreements to comply with the following:

(1) All relevant standards for safe handling and use of the research reagents.

(2) Agreement not to use the reagents in any unauthorized or unsafe way including compliance with Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 26; and Public Health Service Policy on Human Care and Use of Laboratory Animals, implementing 1996 revisions of the Guide for the Care and Use of Laboratory Animals.

(3) Agreement that if commercial use is planned or commercial discoveries result through the use of a reagent, such use will occur only according to the donor-assigned Release Category for the reagent.

(4) Agreement by reagent recipient investigators and their institutions to indemnify and hold harmless the United States, its Contractor, their suppliers, and contributors of reagents from any claims, costs, damages, or expenses. The Contractor shall secure and update/modify these agreements as required by the Project Officer.

(5) State-Institution Compliance Agreement by reagent recipient investigators at public institutions that are unable to accept the terms of the Standard Indemnification Agreement stated above in 4.e.(4), the recipient institution agrees to be responsible for any claims, costs or expenses that may arise from the possession and use of reagents to the extent permitted under Federal and State law.

5. **SHIP AND RECEIVE REAGENTS**

a. Ship and receive reagents, ensuring the assumption of shipping costs by the recipient whenever possible.

b. Ship available reagents within 7 working days from the date requests are received.

c. Insure that shipping complies with Federal and State laws for distribution of Category A-C Agents.

d. Provide, packaged with outgoing reagents, data sheets containing technical information, references and citations of the relevant information for safe handling and use of the reagents, and applicable safety standards. The Contractor shall delineate specific safety standards for the safe handling and use of specific reagents, in compliance with State and Federal regulations.

e. Provide for safe packaging, shipping and distribution of reagents and drugs approved by the Project Officer to eligible research investigators in the U.S. and abroad so that such shipments are coordinated for timely receipt. A secure package tracking system shall be utilized to insure that all materials are delivered to the intended recipient

f. Obtain the appropriate licenses and permits required by local, state and Federal authorities for the safe import, storage and distribution of reagents and drugs. Additionally, the Contractor shall obtain the appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biohazardous and/or radioactive reagents and drugs.

g. Provide 24-hour, seven days a week availability of personnel to pick up and store incoming shipments of reagents from a specified airport or other contract site in a timely manner in order to assure that reagents are maintained at necessary temperature until placed in the Biodefense Reagent Program. Because the incoming shipments usually represent a substantial financial investment, it is essential that the Contractor coordinates shipments so that personnel will be available to receive the arriving package whenever delivered and transport shipment to the Biodefense Resource Program for storage at the required temperature. All shipments when received should be maintained for stability and viability by providing the necessary temperature in transit from the airport or other site to the Biodefense Resource Program. The Contractor shall make changes in their airport shipping/receiving procedures and requirements to remain in compliance with Department of Transportation regulations.

h. Coordinate all shipments so that viability, biological activity or purity of the reagents will not be adversely affected. Send notification by World Wide Web/facsimile/telegram to all foreign investigators to coordinate shipping and receiving of frozen and refrigerated reagents. Advise domestic investigators in the most suitable manner of shipments and arrival dates.

i. Use shipping containers for reagents that comply with current domestic and international transport regulations and pertinent (IATA) International Air Transport Association/International Civil Aviation Organization Dangerous Goods Regulations (http://www1.iata.org/cargo/dg/index.)

j. The shipping containers must provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.

6. **DISSEMINATE PUBLIC INFORMATION CONCERNING REAGENT AVAILABILITY**

a. Promote awareness of the Biodefense Resource Program 's services throughout the scientific community using electronic and print media, and as determined by the Project Officer, leased booths or poster presentations at scientific meetings, symposia and workshops. World Wide Web-based advertisements shall include links to relevant pages.

b. Provide HTML copy to publish and periodically update the Biodefense Resource Program information on the NIAID Home Page on the World Wide Web including but not limited to the Biodefense Reagent Program catalog.

c. Develop and maintain an electronic World Wide Web-based reagent ordering/donating system, LISTSERV news groups and an electronic bulletin board.

d. With approval of the Project Officer, prepare camera-ready hard copy of a catalog of available reagents. The Contractor to arrange for printing through the contract. The catalog shall be prepared annually with a publication date of January of each year. The first catalog shall be published in January 2005. It is anticipated that approximately 1,000 copies will be printed and distributed annually. The Contractor shall distribute the catalogs to the scientific community on the Biodefense Resource Program mailing list (approximately 300 copies), and to others on request.

e. Publish descriptions of portions of the Biodefense Reagent Program collection in relevant scientific journals as determined by the Project Officer.

7. **PROVIDE NECESSARY BIODEFENSE RESOURCE PROGRAM SUPPORT**

a. Support collaborative efforts of the NIAID and the Division of Microbiology and Infectious Diseases to develop/evaluate and expand access to reagents, including but not limited to, reference standards and panels of reagents, such as PCR standards, DNA libraries, viral and microbial isolates, antibodies, and drugs.

b. Periodically get feedback to evaluate services provided by the BRP, including the status and use of reagents, and other services provided by the contract.

c. Provide other related services, within the scope of this contract, as may be deemed necessary by the Project Officer.

8. **PROVIDE SUPPORT FOR BRP-SPONSORED WORKSHOPS**

Under the guidance of the Project Officer, the BRP shall sponsor workshops to distribute protocols and technology; to develop reagents and/or protocols; to prioritize reagent acquisitions; to promote technology transfer; and to promote compliance with regulations for packaging and shipping of infectious substances. The Contractor shall provide support for invited participants, including travel and per diem expenses.

9. **PROVIDE AN INVENTORY AND DISTRIBUTION DATABASE AND MANAGEMENT SYSTEM**

Provide and maintain an on-going computerized inventory and distribution database and processing system on a personal computer (PC)-compatible system that will track and assist in the coordination of the activities under this contract.

a. Keep records for each reagent, including but not limited to the following:

- the source/donor of the reagent
- a full description of the reagent
- category of reagent (e.g. not of human origin, human-derived, biohazardous, radioactive, donor assigned category for commercial use)
- lot number; date of receipt
- quality control information
- storage conditions
- solubility of the reagent when appropriate
- storage location
- restrictions, if any, on disposition and uses
- how dispensed and to whom
- when the reagent was shipped and to whom it was shipped
- by whom it was shipped to
- documentation from the recipient that the reagent was received

b. Have the capability to read and generate bar-coded labels for 1.8 ml reagent vials in different formats including numeric, alpha numeric and colored bar codes. Material (software and hardware) for maintaining these records must be provided by the Contractor.

c. Ensure protection against the loss of data by the duplication of data base files and programs for storage outside of the BRP. The system in its entirety shall be completely documented and capable of being transferred to the Government without interruption.

d. Provide for the security and safety of data on the reagents and information related to the evaluation and use of the reagents. All information regarding the evaluation of the reagents shall be proprietary and treated as such. The Project Officer shall be responsible for determining the level of information regarding a particular reagent that will be made available for dissemination and to whom the information will be made available.

10. **MEET WITH THE PROJECT OFFICER**

The Contractor's key personnel, including the Principal Investigator, shall meet with the Project Officer at periodic intervals to be scheduled after contract award, to review the project and discuss the work to be performed.

11. **ENSURE AN ORDERLY TRANSITION OF THE BIODEFENSE RESOURCE PROGRAM TO A SUCCESSOR CONTRACTOR**

a. At the end of this award, the Contractor shall coordinate an orderly and safe transition from the current incumbent Contractor to the new awardee, including the movement of stored reagent samples, data, and all Government furnished property to a subsequent Contractor or to the Government.

b. The subsequent Contractor shall commence operation in accordance with approved Standard Operating Procedures.

[END OF STATEMENT OF WORK]

ATTACHMENT A-1

SAFETY CONTROLS, STANDARDS, REGULATION OF ACCESS TO CDC CATEGORY A-C AGENTS

a. In order to provide safety controls for protection to the life and health of employees and other persons; for prevention of damage to all property; and for avoidance of work interruptions in the performance of the contract; the contractor shall refer to the following:

(1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH, Fourth Edition http://www.cdc.gov/od/ohs/biosfty/biosfty.htm; http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf
(2) Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.
(3) Appendix A to Part 72, CFR 42, Select Agents http://www.cdc.gov/od/ohs/lrsat/p54605.pdf
(4) Recommendations for the Safe Handling of Parentoral Antineoplastic Drugs, NIH Publication No. 92-2621: http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm
(5) NIH Chemical Hygiene Plan. http://www.nih.gov/od/ors/ds/pubs/chp/index.html

The above, (1) - (5), may be obtained from:

Division of Safety, Office of Research Services
Office of the Director, National Institutes of Health
Bethesda MD 20892-2260
301-496-1357

(6) Occupational Safety and Health Administration (OSHA) Publications:
1) 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule, and;
2) 29 CFR Part 1910, Occupational Exposure to hazardous chemicals in Laboratories, Final Rule.

The above 1) and 2) may be obtained from:

Division of Safety, Office of Research Services
Office of the Director, National Institutes of Health
Bethesda MD 20892-2260
301-496-1357

(7) Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplement.

These may be obtained from:

Division of Safety, Office of Research Services
Office of the Director, National Institutes of Health
Bethesda MD 20892-2260
301-496-1357

(8) Procedures for the Domestic handling and Transport of Diagnostic Specimens and Etiologic Agents, National Committee for Clinical Laboratory Standards, July 17, 1985, Vol. 5.

This may be obtained from:

National Committee for Clinical Laboratory Standards
771 East Lancaster Avenue
Villanova PA 19085

Additionally the contractor must be aware of and comply with these regulations governing the handling, transportation and import/export of etiologic agents. These include:

Title 42 Part 72.6, "The Select Agent Rule"
Effective date: April 15, 1997
Incorporated into the rule January 1, 2002—
Appendix F, Laboratory Security and Emergency Response for Microbiological and Biomedical Laboratories
Appendix I, Guidelines for Work With Toxins of Biological Origin
http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm

Regulations governing the shipment of select agents and biohazards
Application for Registration to receive select agents
http://www.cdc.gov/od/ohs/lrsat/facility.htm ; http://www.cdc.gov/od/ohs/lrsat.htm
Regulation for the importation of etiologic agents
USPHS 42 CFR - Part 71.54 -Importation of etiologic agents, host and vectors of human disease.
USDA, 9 CFR Parts 92, 94, 95, 96, 122 & 120. -Importation or domestic transfer of etiologic agents of livestock, poultry, and other animal diseases
DOC, 15 CFR Parts 730-799 -Export of items on the Australia Group list. Bureau of Export Administration, DOC
DOT, 49 CFR Part 171 – Research and Special Programs Administration, DOT - General information, regulations, and definitions

Rules governing the illegal possession of a biologic agent
Antiterrorism and Effective Death Penalty Act of 1996
Sec. 511. Enhanced Penalties and Control of Biologic Agents
Public Law 104-132; April 24, 1996

USA Patriot Act: Sec. 817. –Expansion of Biological Weapons Statute
http://www.ins.usdoj.gov/graphics/lawsregs/patriot.pdf
S. 1706 - Bioweapons Control and Tracking Act of 2001 (11/15/2001)
H.R. 3448 - Public Health Security and Bioterrorism Response Act of 2001
http://www.cdc.gov/od/ohs/lrsat/bioterro.htm

Limitation on Issuance of Hazmat Licenses (DOT)
License to operate a motor vehicle transporting in commerce a hazardous material - Sec. 1012 - Requires a background records check: Possession by Restricted Person - sec. 175b- No restricted person shall ship, possess, or receive a Select Agent.

Further, the Contractor shall take or cause to be taken such additional safety measures as the Contracting Officer may determine to be reasonably necessary; provided, that if compliance with such additional safety measures results in a material increase in the cost or time of performance of the contract, an equitable adjustment will be made in accordance with the clause of this contract entitled "Changes."

b. Prior to commencement of work, the Contractor will submit in writing its plan for complying with the safety and health provisions of this contract, and shall meet with the Contracting Officer or his/her designated representative to discuss and develop a mutual understanding relative to administration of the overall security and safety program.

c. During the performance of work under this contract, the Contractor shall comply with all procedures prescribed by the Contracting Officer for the control and safety of persons visiting the job site and shall comply with such requirements to prevent accidents as may be prescribed by the Contracting Officer.

d. The Contractor will maintain an accurate record of, and report to the Contracting Officer in such manner as the Contracting Officer may prescribe, all accidents and incidents resulting in death, traumatic injury, occupational disease, and/or damage to all property incident to work performed under the contract.

e. The Contracting Officer shall notify (if otherwise, confirm in writing) the Contractor of any noncompliance with the provisions of this clause and corrective action to be taken. After receipt of such notice, the Contractor shall immediately take such corrective action. (Such notice, when delivered to the Contractor or its representative at the site of the work, shall be deemed sufficient for the purpose.) If the Contractor fails or refuses to comply promptly, the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action has been taken. No part of the time lost due to any such stop order shall be the subject of claim for extension of time or for costs or damages by the Contractor.

f. The Contractor shall insert the substance of this clause in each subcontract involving the use of hazardous materials or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

[END OF ATTACHMENT A-1]

Reporting Requirements
Biodefense and Emerging Infections Research Resources Program
DMID-03-34

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period as stated below:

A. MONTHLY REPORTS. By the fifteenth calendar day after completion of each month, the Contractor shall submit three copies of a report of work performed in the previous month. These may be changed to quarterly reports at a later time during the life of the contract Each monthly report shall consist of:

1. A cover page containing:

   (a) Contract number and title;
   (b) Period of performance being reported;
   (c) Contractor's name and address;
   (d) Author(s); and
   (e) Date of submission.

2. Information that shall include a brief summary of the work performed during the reporting period but not be limited to the following:
   (a) An inventory report of the quantity and types of each reagent stored as of the last day of each month;
   (b) A list of reagents assayed during the month, type of assay and results of the assay;
   (c) A list of all investigators and sites that have applied for certification as recipients of Category A, B & C CDC Select Agents Select Agents (Appendix A to Part 72, CFR 42, **http://www.cdc.gov/od/ohs/lrsat/p54605.pdf**).
   (d) A summary of reagents shipped which will have the following information for each reagent:

      (i) Quantity of the reagent;
      (ii) Date of shipment;
      (iii) Date of receipt of shipment;
      (iv) Name and address of the recipient; and
      (v) Problems associated with any shipment.

   (e) A summary of reagents that were acquired during the month that will list the following information for each:

      (i) Quantity of reagent;
      (ii) Source of reagent;
      (iii) Description of reagent;
      (iv) Quality control information;
      (v) Restrictions on disposition and use; and
      (vi) Unit and total cost of reagent.

   (f) Cumulative list of publications by registrants acknowledging Biodefense Resource Program as a source of reagents.
   (g) Feedback on reagents use.
   (h) Maintenance problems encountered and corrective action taken.
   (i) Need for replacement or repair of Government furnished equipment.
   (j) Description of current technical or administrative problems encountered, their resolution or the proposed corrective action.

B. FINAL REPORT. The Contractor shall submit three copies of the final report that documents and summarizes the results of the entire contract for the period of performance. This report will provide a final inventory and contain a cover page described in A.1. above and the information required in A.2. above. The final report will also contain a Summary of Salient Results.

1. The final report shall be submitted on/before the completion date of the contract.

2. If the Contractor is unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons thereof. The Contractor will not be reimbursed for costs related to preparation of final deliverables incurred after the completion date of the contract without prior written approval and a modification to the contract authorized by the Contracting Officer.

3. The Contractor will not be reimbursed for costs related to preparation of final deliverables incurred after the completion date of the contract without prior written approval and modification to the contract authorized by the Contracting Officer.

C. OTHER DELIVERABLES. The Contractor, subject to the Contracting Officer's approval, shall deliver to the Government or its designee by the expiration date of the Contract, the following items:

1. Preserved reagent samples;

2. Biodefense Reagent Management System and documentation on the computer systems/files;

3. Computerized listing of accurate and updated information on reagent inventory, including activities of the Biodefense Resource Program, data files, data bases, original data and any necessary information related thereto; and

4. Labeled and inventoried paper files.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee

52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)

52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 05/2002]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

ALTERNATE IV (OCTOBER 1997) of FAR Clause 52.215-21, REQUIREMENTS FOR COST OR PRICING DATA OR INFORMATION OTHER THAN COST OR PRICING DATA--MODIFICATIONS (OCTOBER 1997) is added.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **[Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

ALTERNATE I (OCTOBER 1998), FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCTOBER 1999).

FAR 52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (OCTOBER 1999).

FAR 52.223-3, Hazardous Material Identification and Material Safety Data (JANUARY 1997), ALTERNATE I (JULY 1995).

FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

FAR 52.247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.223-70, Safety and Health (JANUARY 2001)

HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

(a) **Definitions**. As used in this clause--

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: February 14, 2003] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

ELECTRONIC SUBMISSION: *In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.*

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DMID-03-34
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Janet M. Mattson Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Janet M. Mattson Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES
[INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided by the Contract Specialist.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-03-34
RFP Title: Biodefense and Emerging Infections Research Resources Program

Please complete and return this page by **Friday, February 14, 2003**. NIAID appreciates knowing if your institution intends to submit a proposal, as this will assist the NIAID in planning for proposal evaluation.

[ ] OUR COMPANY/INSTITUTION **DOES INTEND** TO SUBMIT A PROPOSAL Your expression of intent is not binding.
[ ] OUR COMPANY/INSTITUTION **DOES NOT INTEND** TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASON(S): _____
_____
_____

Company/Institution Name (print): _____
Address (print): _____
_____

Name of Proposed Project Director or Principal Investigator (print):
_____
Telephone and FAX Number: _____
E-mail Address: _____
Signature/Date: _____

Since your proposal will be submitted electronically, include the name and e-mail of the individual to whom NIAID should provide electronic proposal instructions (i.e. login code and password).

Name, Title: _____
Telephone and FAX Number: _____
E-mail Address: _____

List individuals (currently on staff with your institution) whom you plan to name in the proposal. Identify your collaborators, subcontractors and/or consultants. List the names of individuals (currently on staff) whom they plan to include in their proposal(s). Use extra pages if necessary. The NIAID uses this information for proposal review planning, specifically, to create a list of potential review panelists. The NIAID is careful to avoid conflicts of interest when assembling these panels. Therefore, it's important that you only name those institutions and individuals most likely to be part of your proposal. Contact the individual named below with any questions.

_____

_____

COMPLETE AND RETURN THIS SHEET VIA FAX OR E-MAIL TO:
CMB, DEA, NIAID, NIH, DHHS
Attention: Janet M. Mattson, Contracting Officer
Reference: RFP NIH-NIAID-DMID-03-34
6700-B Rockledge Drive, MSC 7612, Room 2230
Bethesda, MD 20892-7612 FAX# (301) 480-5253, Email: jm32u@nih.gov

FORM VERSION DATE: October 22, 2002

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals

in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(12) Guidance Regarding Federal Government Collaborations: In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or appearance of a conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter **must** be signed by both the designated agency ethics official (DAEO) and the head of the agency (or his/her designate). The NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or appearance of a conflict of interest.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 54171 .
(2) The small business size standard is 500 employees .

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE AWARD will be made from this solicitation and that the award will be made on/about September 30, 2003 .

It is anticipated that the award from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 196,000 labor hours/seven years. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

m. USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement (completion) type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

a. Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- **For an Institution of Higher Education: The form <u>MUST</u> be completed in its entirety.**
- **For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.**

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "<u>INSTRUCTIONS</u>:"

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Care of Live Vertebrate Animals**

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(10) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(11) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(12) **Selection of Offerors**

a) The acceptability of the scientific and] technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the FedBizOpps.

(13) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation as an Attachment to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(14) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(15) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(16) **Salary Rate Limitation in Fiscal Year 2003** *

Offerors are advised that pursuant to P.L. * , no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. * applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. * states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I*."

Link to Executive Schedule Salaries: http://www.opm.gov/oca/PAYRATES/index.htm

**pending passage of FY-2003 legislation.*

(17) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(18) **Past Performance Information**

a) Offerors shall submit the following information as part of their BUSINESS proposal.

A list of the last five (5) contracts completed during the past three (3) years and the last three (3) contracts awarded currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as exceeding $500,000.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(19) **Prohibition on Contractor Involvement with Terrorist Activities**

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

(20) **Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program**

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDCs that can be found at http://www.cdc.gov/od/ohs/lrsat.htm and NIH's OBA that can be found at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html .

(21) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. **ADDITIONAL COST AND TECHNICAL PROPOSAL INSTRUCTIONS**

THE FOLLOWING INFORMATION IS SPECIFIC FOR PURPOSES OF RESPONDING TO THE RFP. ALL THE OFFEROR(S) SHOULD PROVIDE SPECIFIC DOCUMENTATION IN THEIR PROPOSAL WITH REGARDS TO THESE ITEMS.

(1) **RELATED REFERENCE MATERIALS:** Offerors interested in responding to this RFP are encouraged to view the 2002 "NIAID Biodefense Research Agenda for CDC Category A Agents" (http://www.niaid.nih.gov/dmid/pdf/biotresearchagenda.pdf) and visit the NIAID Web site describing additional developments of the Biodefense Research Agenda http://www.niaid.nih.gov/publications/bioterrorism.htm

(2) **UNIFORM ASSUMPTION - COST:** Based upon the experience gained from other reagent program contracts, it is somewhat difficult to predict or identify in advance the types and amounts of reagents, and the numbers of cell expansion quality control analyses or reagents that will be required during the contract term. Therefore, based upon historical experience, and for the purposes of the offeror preparing a budget, the government estimates expending $10,000,000 in Year 1 for activities under sections 1 and 2 (reagent purchase, production / expansion and quality control reagents) of the Statement of Work. It is estimated that this budget item will total $76,624,622 total for seven years, which includes 3% yearly inflationary adjustments over the life of the contract.

Based on the experience with other reagent program contracts, 87% of the acquired reagents were donated by investigators (50% of these were then expanded with contract funds); all other "acquisition" of reagents was accomplished through purchase and / or services. The acquisition effort therefore includes solicitation or donations, purchase orders / subcontracts for producing reagents, and expansion of reagents; renewable reagents provided to the BRP in small amounts will require expansion.

The number of reagent samples stored in the Biodefense Resource Program will initially have up to 5000 samples obtained from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Ft. Detrick, MD. It is anticipated that new reagents will enter the program on a regular basis, at an estimated rate of 30-50 reagents (50-200 reagent samples) received monthly from domestic supplies during the first year of this contract. The offeror should anticipate a 15% increase annually in the number of reagents acquired and samples stored in the BRP to an estimated total of 185,000 samples during the term of the contract. At the beginning it is anticipated that the BRP will need 50 cubic feet of low-temperature storage space. It is estimated that the contract will require expansion of low-temperature storage space to about 200 cubic feet by the end of this contract.

For the purposes of preparing a budget, assume two, one-day workshops annually, 10 out-of-town invitees to be held in the Washington D.C. area.

The offeror should provide with the technical proposal a plan for the movement of the BRP at the conclusion of "This" contract to a new site; include the costs for this move in the business proposal.

This contract will support the purchase of ADP equipment to ensure, for CDC Category A agents, CDC Select Agents and NIAID Priority Agents and NIAID Emerging Pathogens, the complete tracking and validation of requests for reagents, verification of reagent shipment and arrival and follow-up on the disposition of the materials shipped. The offeror must justify the choice of database and management software. All software should be Web-based.

(3) **COMMERCIAL FIRMS – POTENTIAL CONFLICTS:** If the offeror is a commercial firm selling or distributing biodefense and emerging infectious disease-related reagents, the offeror should address in detail in the technical proposal how potential conflicts of interest will be resolved between commercial acquisition and distribution of reagents and BRP acquisition and distribution of similar reagents. For example, the offeror must address how the offeror will identify and obtain potentially commercially valuable reagents for BRP distribution instead of for the offeror's commercial use.

(4) **SUBCONTRACTING**: The Government is aware that no single organization or institution may have the expertise and facilities required to perform all the requirements set forth in this statement of work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. For any proposed subcontractor (or subcontractors) to produce / expand reagents, similar technical information should be provided as part of the Technical Proposal as that required from the Prime Contractor, i.e., technical approach, methods, knowledge, experience, personnel qualifications, specific responsibilities, work to be performed, facilities, resources, demonstration and documentation of U.S. Government approval to possess and work with CDC Category A agents (**http://www.bt.cdc.gov/agent/agentlist.asp**), the fulfilling the requirements of the Patriot Act (USA Patriot Act: Sec. 817. –Expansion of Biological Weapons Statute http://www.ins.usdoj.gov/graphics/lawsregs/patriot.pdf) and access to Select Agents (Appendix A to Part 72, CFR 42, **http://www.cdc.gov/od/ohs/lrsat/p54605.pdf**) prior to beginning work as a subcontractor. Cost details should also be provided by the subcontractor and submitted with the business proposal. The review and selection criteria for adding additional subcontractors during the contract performance must be clearly delineated. Additionally, the relationship between the subcontractor(s) and the Prime Contractor in conducting the Statement of Work must be clearly delineated. The prime contractor will be responsible and accountable for the timeliness and quality of all services and products provided by the subcontractors under this contract.

(5) **PERSONNEL:** In responding to the RFP, the Offeror must describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. In addition the Offeror must describe an administrative framework indicating clear lines of authority.

Documentation must also be provided on the qualification, experience, education, competence, availability and decision-making authority of the Principal Investigator, Registration / Tracking Manager, Senior Scientists, Registration / Tracking Assistants, Shipping Manager, Administrative Assistant, Security Officer, Materials Handler and Inventory Assistant. Resumes and explanations of previous efforts provided for the Principal Investigator, Registration / Tracking Manager, Senior Scientists, Registration / Tracking Assistants, Shipping Manager, Administrative Assistant, Security Officer, Materials Handler and Inventory Assistant must be clearly demonstrate relevant knowledge, training, experience and specific accomplishments. Documentation must include all previous and current projects of a similar nature, including where applicable, the contract or grant number, sponsoring agency, project officer and name and description of the project.

(6) **STANDARD OPERATING PROCEDURES:** The Offeror should furnish its proposed standard operating procedures relating to the conduct of this contract as part of the technical proposal. The Offeror's technical proposal should also include samples of inventory control procedures and chain of custody

d. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(4) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(7) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(8) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(9) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(10) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(11) Certification of Visa's for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. PAST PERFORMANCE FACTOR

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal was determined to be unacceptable by the peer review panel.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

Listed below are past performance factors to be used for evaluation purposes.

Past Performance Factors

Record of conforming to specifications and to standards of good workmanship
Record of forecasting and controlling costs under cost-reimbursement contracts
Adherence to contract schedules, including the administrative aspects of performance
Reputation for reasonable and cooperative behavior and commitment to customer satisfaction
Business-like concern for the interest of the Customer

3. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Complexity and variety of the work SDB concerns are to perform
(b) Extent of participation of SDB concerns in terms of the value of the total acquisition.

4. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERA **WEIGHT**

A. TECHNICAL APPROACH **55 Points**

The technical adequacy, feasibility, safety and effectiveness of the detailed and specific plans demonstrating knowledge, experience and competence, standard operating procedures, and quality control measures proposed for operation of a NIAID Biodefense and Emerging Infectious Diseases Resource Program (BRP), including:

(1) Initial Reagent Management, Production and Quality Control (30 points)

Identification, prioritization, and acquisition of reagents from domestic and international sources; overall management plan by offeror of all subcontractors including methods of communication, reagent production and quality control oversight and reporting; production/expansion of reagents; characterization, release and stability of reagents; evaluation of the quality and activity of the reagents; demonstrated knowledge, experience and competence of the Contractor and any and all Subcontractors in the production and quality control analyses of biological and chemical reagents, including GMP-produced materials.

(2) BRP Contract Management (25 points)

a) Start up, Facility Operations and Transition

Quality of the Standard Operating Procedures submitted to initiate operation of the BRP; adequacy and feasibility of proposed schedule and task-linked budget items; ability to manage a contract in accordance with the proposed schedule and budget; reporting and communication of schedule and budget status to the government of a regular (at least monthly) basis; coordination of the operation of the BRP through interactions with the biodefense and emerging infectious diseases research communities in academic, government, biotechnology and pharmaceutical companies (worldwide), technology transfer officials, and the Division of Microbiology and Infectious Diseases, including sponsoring workshops and awareness-promoting activities; plan for providing editorial and publishing services for the catalog of reagents; operations plan for resolving

potential conflicts of interest if a commercial organization is acquiring potentially valuable reagents for offeror's commercial use rather than for this program.; at the end of this contract, effecting smooth transitions between Contractors, including providing assistance to the successor Contractor to ensure a safe and efficient move of the BRP Program; and coordinating an orderly transition .

(b) Inventory Control and Distribution (10 Points)

Maintaining and updating secure internal information database systems and on the World Wide Web, to track all information that relates to the activities of the BRP, including an inventory of reagents, shipment and receiving of reagents, and assay information; documented ability of the offeror to manage and operate a facility which receives and ships biohazardous materials.

B. PERSONNEL QUALIFICATIONS **25 Points**

(1) Training and Experience - Principal Investigator (15 Points)

Documented training, experience and availability of a Principal Investigator. The technical and administrative competence to operate the BRP, or a Project of comparable size and complexity; the proposed P.I. shall have a Ph.D. or its equivalence, and postdoctoral research experience preferably in the microbiological sciences, or biological sciences; demonstrated knowledge and research experience in microbiology and infectious disease research in order to identify and prioritize Biodefense and Emerging Infectious Diseases reagents and to provide technical assistance and oversight; documented experience and expertise in working at the Biosafety Level (BSL)-2/3 containment level and ability to provide specific training and guidance in the safe and proper handling of pathogenic agents.

(2) Training and Experience - Support (10 Points)

Documented training, experience and availability of other professional and support staff necessary to successfully carry out proposed roles, including laboratory and research experience and expertise, editorial and demonstrated scientific writing (preferably experience in infectious diseases) to prepare a BRP catalog and promotional literature; laboratory competence and familiarity with safety regulations; and World Wide Web site maintenance experience; support personnel include personnel who are knowledgeable of and in compliance with current IATA and DOT training requirements for shipping infectious substances.

C. FACILITIES AND RESOURCES **20 Points**

Documented availability of adequate facilities, equipment and resources necessary to safely operate, maintain and expand this Biodefense Resource Program; facilities to ship, receive and store hazardous and infectious agents, and maintain their activity and viability. The offeror offer shall provide:

- a list of equipment and resources dedicated to the project and a detailed floor plan of the proposed facility showing the location of the equipment and resources; facility modifications that would be accomplished prior to initiation of the contract;

- If the use of a BSL-3 facility is contemplated by a contractor or subcontractor, documentation of the facility's design and operational procedures shall be included; if a proposed BSL-3 facility is not yet operational, documentation that the facility shall be commissioned, to verify that the design and operational parameter shall be met prior to operation, in a manner similar to or in accordance with that detailed in the NIH Model Commissioning Guide http://des.od.nih.gov/eWeb/research/farhad2/Commissioning/nih_cx_guide/ComGuideTitle.htm, must be included; if a BSL-3 facility is fully operational, documentation that the facility has been re-verified within the last 12 months against a commissioning guide as modified by the offeror's operational experience shall be included;

- information regarding ownership/lease of the facility which demonstrates availability for the duration of the proposed contract;

- plan for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents;

- logistic plan for storage, packaging and shipping of reagents nationally and internationally, including notification mechanism for date reagent received and condition of reagent upon receipt; logistic plan for receiving, processing and storing incoming reagent shipments; and

- information concerning all physical and electronic security systems to prevent unauthorized entry into the facility and security systems to prevent unauthorized access to the BRP computer databases and other associated computer systems, programs and files.

TOTAL: 100 Points

[END OF SOLICITATION]